



May 12, 2006

Mark Bradley, Associate Deputy Administrator
USDA-AMS-TMP-NOP
Room 4008-South Building
1400 Independence Avenue, SW
Washington, DC 20250-0020
Comments on: Docket TM- 06-06-PR

Dear Mr. Bradley:

OMRI appreciates the opportunity to comment on the proposed changes to the National Organic Program rule published in *Federal Register* docket TM-06-06-PR (71 *Federal Register* 24820-24824). We understand that the proposed rule is to address the court mandated regulatory changes of June 9, 2004 as well as those in response to the November 10, 2005 Congressional amendment of the Organic Foods Production Act (OFPA). The USDA has a clear need to revise the rule yet it faces serious constraints. As a non-profit organization that has a mission to provide professional, independent, and transparent review of materials allowed to produce, process, and handle organic food and fiber, we offer technical comments to aid with the implementation of the NOP rule.

OMRI urges that the Secretary revise the proposal published in Docket Number: TM-06-06-PR to be clear and consistent with the statute, and compliant with the court's ruling. OMRI supports the intent of the National Organic Program to adhere to the public process as set out in the Organic Foods Production Act of 1990 (OFPA). With respect to this Docket, as we have in previous comments, we would like to address the procedure and structure of the National List. OMRI is concerned that the language as proposed is not clear and will cause inconsistent implementation of the USDA standard for organic production.

Dairy Herd Conversion

OMRI understands that the transition of dairy operations require special consideration. The Organic Foods Production Act was revised in 2005 to permit the simultaneous transition of land and animals during the last twelve months of the conversion of land used to produce food and forage, particularly the land on which transitioning animals graze. OMRI supports the intent to count this land in transition as sufficient to provide sustenance for animals that are also in transition.

It is OMRI's understanding that the court ruling does not permit a two-track standard for replacement animals to be applied to organic operations, and instead required all dairy operations to be treated consistently. The proposed rule does not address this issue. The recent public announcement that this will be addressed soon with an ANPR is welcomed.

Non-organic Agricultural Ingredients

OMRI does not support the proposed revision for non-organic agricultural ingredients contained in section 205.606. While it is important for 205.606 to be a comprehensive list of non-organic agricultural ingredients used to make processed products that are labeled 'organic,' the proposal goes too far in extending the requirements also to products that are labeled as 'made with organic [specific ingredients or food group(s)].'

The rule as it currently reads is ambiguous and subject to widely varying interpretations. While the Harvey decision required clarification that only non-organic agricultural ingredients on the National List could be used in processed products that are labeled as 'organic' the ruling did not apply to the 'made with organic [specific ingredients or food group(s)].'

The use of the word 'product' both in reference to the agricultural product that is the ingredient and to the final processed product creates ambiguity and is confusing. A given agricultural product in question is an 'ingredient' and should be referred to as such.

OMRI would also like to comment on the content of the list. The NOSB has recommended that gelatin and orange unbleached shellac be added to the National List. For ease of reference, the lettering should be removed and the list maintained in alphabetical order, similar to the construction of 205.605.

OMRI urges the NOP to work with the NOSB in developing further clarification in defining what is 'agricultural' and what constitutes 'commercial availability' before publishing a final rule, and adopt a recommendation that has the broad support of the organic industry as well as the rest of the organic community.

Section 205.606 should be revised to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic ~~or made with organic ingredients~~.

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic" ~~or "made with organic (specified ingredients or food group(s))"~~, only in accordance with any restrictions specified in this section, and only when the ~~product~~ ingredient is not commercially available in organic form.

~~(a)~~ Cornstarch (native)

Gelatin

~~(b)~~ Gums - water extracted only (arabic, guar, locust bean, carob bean)

~~(c)~~ Kelp - for use only as a thickener and dietary supplement

~~(d)~~ Lecithin - unbleached

~~(e)~~ Pectin (high-methoxy)

Shellac, Orange Unbleached

Synthetics Used in Handling

Finally, OMRI wishes to comment on the reference made in the preamble to the use of synthetic substances in processing. The *Federal Register* notification states that “On November 10, 2005, Congress amended the OFPA by permitting the addition of synthetic substances appearing on the National List for use in products labeled ‘organic.’” (71 *Fed. Reg* 24821).

Congress amended Section 2111 (7 U.S.C. 6510) of the OFPA on November 10, 2005 to read:

“(a) IN GENERAL. - For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title -
“(1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling of the product;”

The docket assumes that no revision is necessary in response to the court order. The USDA may want to consider that there remains a discrepancy between the regulation, which refers to ‘substances used in or on organic food,’ and the amendment to the statute, which refers to ‘ingredients.’ In *Harvey* the Court ordered that regulations establishing criteria to review synthetic substances found at §205.600 were contrary to the plain language of the OFPA (396 *F.3d* 40). OMRI concurs with the USDA’s understanding that the Congressional amendment to the OFPA permitting synthetic ingredients eliminates the need for the NOP to remove the regulations at §205.600(b). OMRI supports retention of the criteria but, in light of the court’s ruling and amendments by Congress, believes that the criteria need to be more clearly applied to ingredients.

The criteria were based on a recommendation made by the NOSB in February 1999 (<http://www.ams.usda.gov/nosb/archives/processing/synthetic.html>). The recommendation followed after a motion to recommend that synthetic ingredients in organic processed food failed by a vote of 5-6, with one member abstaining (<http://www.ams.usda.gov/nosb/archives/minutes/Feb99/mins.html>).

Thus, the NOSB intended to see the criteria applied to all synthetic substances used in or on organic food and not limited to processing aids or adjuvants. OMRI strongly supports stringent regulatory review criteria for use during the evaluation of any synthetic substance proposed for inclusion on the National List. Now that the OFPA has been revised to permit the use of synthetic ingredients, the regulation needs to be revised to evaluate petitions of synthetic ingredients.

OMRI believes there needs to be a technical correction in §205.600(b) to be consistent with the agency’s interpretation of the Congressional amendment. The regulation should be amended as follows:

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used ~~as a processing aid or adjuvant in handling~~ will be evaluated against the following criteria:

(1) * * *

The NOP website contains, as of this writing, a policy statement entitled, “Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances are Used as Ingredients in Processed Food Products.” (<http://www.ams.usda.gov/nop/NOP/PolicyStatements/SyntheticSubstances.html>). OMRI requests that for the sake of clarity and to comply with both the court order and the amendment to OFPA that the USDA remove the statement from its website.

OMRI also requests that the NOP recognize the fact that to appear as an ingredient on the label declaration, that ingredient must be either organically produced or appear on the National List. In particular, the product of the synthetic reaction of two substances on the National List would need to be petitioned, reviewed, recommended, and appear on the National List as well. Petitions for such substances should be referred to the NOSB and be evaluated according to the criteria at 7 CFR 205.600(b).

Consistent with the agency’s interpretation of the Congressional amendments, §205.605 should under go the following amendment:

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used ~~as ingredients~~ in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

OMRI has commented previously on the need for the USDA to remove the food contact substance policy and consistently apply the criteria in the Organic Foods Production Act and the NOP rule to all synthetic substances used in or on processed food labeled as organic. Consistent with this amendment the NOP should also further clarify the status of synthetic substances by rescinding its “draft” policy allowing some synthetic substances at <http://www.ams.usda.gov/nop/NOP/PolicyStatements/SyntheticSubstances.html>.

Our understanding is that USDA officials have publicly stated that the current Food Contact Substance policy is not final and the policy was posted as part of an ongoing deliberation about how the Act and Rule operate. At an NOSB meeting last October, the NOP staff has assured the NOSB and the public that they would follow the process mandated by the statute to add synthetic substances to the National List. We respectfully ask for affirmation of that understanding and commitment in response to these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Dave H. DeCou". The signature is fluid and cursive, with the first name "Dave" and last name "DeCou" clearly distinguishable.

Dave DeCou
Executive Director